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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,381	08/13/2001	Michael A. Kapin	1973	1047

7590 06/15/2006

R&D Counsel (Q-148)  
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EXAMINER

GRAFFEO, MICHEL

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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**MAILED**  
**JUN 15 2006**  
**GROUP 1600**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/929,381  
Filing Date: August 13, 2001  
Appellant(s): KAPIN ET AL.

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Teresa J. Schultz  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 20 March 2006 appealing from the Office action mailed 18 August 2005.

**(1) Real Party of Interest**

The real party of interest has been identified by Appellants as Alcon, Inc.,

**(2) Related Appeals and Interferences**

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments**

The statement of the status of amendments contained in the brief is correct. Examiner acknowledges the amendment to claim 1 and cancellation of claim 9.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct. The present claim sets contains one independent claim, claim 1. The independent claim does not contain any instances of means plus function or step plus function and therefore have not been addressed, (see 37 C.F.R. §41.37(c)(v)).

**(6) Grounds of Rejection to be Reviewed on Appeal**

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in Appendix I to the brief is correct.

**(8) Evidence Relied Upon**

US Patent No. 5,994,379 (Bayly et al) issued 30 November 1999

US Patent No. 6,207,700 (Kalgutkar et al) issued 27 March 2001

US Patent No. 6,342,524 (Hellberg et al) issued 29 January 2002

**(9) Grounds of Rejection**

The following grounds of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 112***

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is still confusing as to whether the "derivative thereof of the formula..." is limited to compounds having the recited formula.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,994,379 (Bayly et al) or 6,207,700 (Kalgutkar et al) in view of 6,342,524 (Hellberg et al).

Bayly (column 9, lines 17-19) discloses that COX-2 inhibitors are useful to treat diabetic retinopathy. Bayly further discloses the recited routes of administration (column 9, lines 46-50). Bayly does not disclose the instant COX-2 inhibitors.

Kalgutkar (column 1, lines 16-26, column 11, lines 21-39) discloses that **COX-2 inhibitors** are antiangiogenic.

Additionally, Hellberg (column 5, line 20, column 6, column 8, lines 10-30) discloses that the instant compound is a COX-2 inhibitor and further discloses ophthalmic administration and the instant dosage.

In the absence of a showing of unexpected results commensurate in scope with the claims it would be obvious to one of ordinary skill in the art to use the compounds of Kalgutkar in the method of Bayly to yield the instant method. That is because Kalgutkar discloses that the instant COX-2 inhibitors are antiangiogenic and Bayly discloses that COX-2 inhibitors are useful to treat angiogenic ophthalmic conditions like diabetic retinopathy. Additionally, Hellberg discloses ophthalmic administration and the instant dosage of the instant COX-2 compound.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-19 of copending Application No. 10/344,881. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method of treating an angiogenesis-related disorder using the compound of claim 1 includes the method of the claims of '881 using 2-amino-3-benzoyl-phenylacetamide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/417,466. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method of treating an angiogenesis-related disorder using the compound of claim 1 includes the method of the claims of '466 using amfenac.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

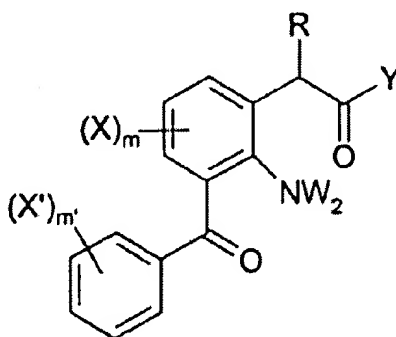
## **(10) Response to Argument**

The Definiteness Rejection as Applied to Claim 9

Claim 9 has been canceled and to such extent, the rejection under 35 U.S.C. §112 is withdrawn with regard to claim 9.

The Obviousness Rejection over Bayly, Kalgutkar and Hellberg

Claims 1-3 and 5-8 are directed to the treatment of ophthalmic angiogenesis-related conditions comprising the compound having the following general structural formula:



and to that extent necessarily involves the administration of the above compound so that said compound reaches the eye. As taught in Hellberg, the above compound (an example of which is nepafenac), is administered in the same concentration as claimed (i.e. topical ocular administration of 0.3% of nepafenac). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. To that extent, the mere administration of the claimed

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compound to a patient in any concentration and via any route of administration would anticipate claims 1-3, 5 and 7 and obviate claim 8 at least. More particularly, instant claim 5 is directed to the topical administration of the active agent to the eye.

Heretofore there is no difference between the teachings in Hellberg and the claim limitations since Hellberg teaches the administration of the claimed compound via the claimed route of administration. Given the premise that compounds having the same structure will have the same functionality, the administration taught in Hellberg will necessarily result in treatment of ophthalmic angiogenesis-related disorders in the patient being treated.

Applicant's contention that Bayly does not teach the compounds of the present invention and that Kalgutkar does not teach the use of the compounds to treat ophthalmic angiogenesis related disorders. While the Examiner agrees thereto, it is the combination of the references that teaches one of ordinary skill in the art that COX-2 inhibitors, such as the one claimed, are efficacious for the treatment of angiogenetic related diseases such as diabetic retinopathy and that the compounds can be administered topically to the eye. In particular, Kalgutkar teaches not just that the compounds have anticancer properties as Applicant puts forth, but also teaches that the compounds have an antiangiogenic effect (see col 1 line 25). As combined, the references teach that COX-2 inhibitors such as nepafenac are efficacious in the treatment of angiogenesis and proliferative disorders such as diabetic retinopathy (Bayly).



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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hellberg teaches that any NSAID is included in the scope of the invention of this Patent (see col 5 lines 36-50):

The present invention is directed, therefore, to methods of treating glaucoma, comprising concurrent or combined administration of therapeutically effective amounts of a prostaglandin analog and a prostaglandin synthesis inhibitor. The preferred methods of the present invention comprise one or more prostaglandin analogs in combination with one or more prostaglandin synthesis inhibitors. Preferred among the prostaglandin analogs are the F-type prostaglandin analogs. Preferred among the prostaglandin synthesis inhibitors are the non-steroidal anti-inflammatory agents, especially those which inhibit PGE synthesis. It will be appreciated, however, that any IOP lowering effective prostaglandin in combination with any prostaglandin synthesis inhibitor for the treatment of glaucoma is within the scope of the present invention.

As noted above, Bayly teaches other COX-2 inhibitors for the treatment of proliferative disorders, such as diabetic retinopathy and tumour angiogenesis. To that end, the direction in Hellberg that it "will be appreciated ... that any IOP lowering effective prostaglandin [NSAID] ... is within the scope of the present invention." is motivation to combine the references and is proper all though applicant's reasoning for combining might be different. The fact that applicant has recognized another

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advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Terminal Disclaimer

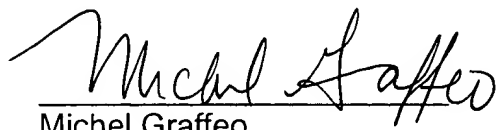
The Terminal Disclaimer is noted and the Double Patenting rejection will be withdrawn upon approval of same.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
Michel Graffeo  
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8 June 2006